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Justin Hanes

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SGAGIAS, MAGDALENE K

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/587,512	Applicant(s) HANES ET AL.	
	Examiner Magdalene K. Sgagias	Art Unit 1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 March 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) 3,4,6,11,14-16,19 and 23-25 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,5,7-10,12,13,17,18 and 20-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 26 July 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>07/26/2006;12/15/2009</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-25 are pending.

1. Applicant's election with traverse of group I claims 1-2, 5-10, 12-13 and 17-22 in the reply filed on 04/02/2010 is acknowledged. The traversal is on the ground(s) that that a search and examination of all claims would place no undue burden on the Examiner. This is not found persuasive because for example the compositions of the group's I-V are not necessarily used only to practice the method steps for transfecting a cell comprising administering to the cell a polymeric particle of claim 1 or 16 of group V. For example, at least the composition of group I can be used in an in vitro assay system. Therefore, it would have been undue burden for the examiner to search and examine both inventions in a single patent application. Furthermore, the examiner has noted that where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejections are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312. The likelihood of finding documents that are simultaneously relevant to two inventions that are not truly similar to one another is very small. For example, the different inventions of Groups I-V rely on structurally unrelated polymeric particles that exert different effects and have different modes of operation, and they are not disclosed as usable together. Furthermore, they are not obvious variants of one another. Groups I-VIII recite divergent subject matter. The prior art applicable to one invention would not likely be applicable

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to another invention. The inventions are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph. The requirement is still deemed proper and is therefore made FINAL.

Claims 3-4, 6, 11, 14-16, 19, 23-25 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 04/02/2010.

Claims 1-2, 5, 7-10, 12-13, 17-18, 20-22 are under consideration.

Applicant's election of species "poly(D,L-lactic-co-glycolic) acid" for the polymer core; "a therapeutic agent" for the bioactive agent; "a small molecule" for the therapeutic agent; "polyethylene glycol" for the surface altering agent; and "chemoattractants" for the adjuvant is acknowledged.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims **1-2, 7-8, 13, 17, 20, 21** are rejected under 35 U.S.C. 102(e) as being anticipated by **Alavattan et al** (US 7,060,299, filed 12/31/2003).

Alavattan et al discloses the encapsulation of spray dried chymotrypsin particles in the copolymers containing lactic acid and glycolic acid residues (poly(lactic acid-co-glycolic acid) or

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PLGA) coated with a cationic hydrophobic surfactant (CTAB) (column 13, example 6).

Alavattan et al teaches that the microparticles containing gum arabic and the cationic surfactant (CTAB), not only control the release of the protein from PLGA microparticles, but also stabilize it prior to release over a period of at least about 3 weeks (Table 7) (**claims 1-2, 13, 20, 21** of the instant invention). Alavattan teaches therapeutic bioactive agents include small molecules such as monosaccharides disaccharides and detergents) (column 7, lines 60-66) (**claims 7-8** of the instant invention). Alavattan teaches the microparticles have a particle size range of about 1 to 150 um preferably particle size range of about 5 to 50 um (column 10, lines 6-11) (**claim 17**). Alavattan et al teach the generation of biodegradable and biocompatible microparticles that contain stabilized proteins and also control the kinetics of release of proteins over a period of several weeks under physiological conditions (column 1, lines 11-20). Alavattan et al teach stable protein microparticles encapsulated in hydrophobic poly(lactic-co-glycolic) acid polymers shows almost complete release of protein (about 80% of encapsulated protein is released after 28 days) and can release the protein in a near linear fashion over a period of about one month (column 1, lines 11-20). Alavattan et al suggest a "biologically active protein" in the PLGA microparticles includes proteins and polypeptides that are administered to patients as the active drug substance for prevention of or treatment of a disease or condition as well as proteins and polypeptides that are used for diagnostic purposes, such as enzymes used in diagnostic tests or in vitro assays as well as proteins that are administered to a patient to prevent a disease such as a vaccine (column 6, lines 39-46).

Thus, Alavattan anticipates claimed invention.

Claim Rejections - 35 USC § 103

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The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-2, **5**, 7-8, 13, 17, 20, 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Alavattan et al** (US 7,060,299, filed 12/31/2003) in view of **Newman et al** (J Biomed Mater Res, 60: 480-486, 2002).

Alavattan et al discloses the encapsulation of spray dried chymotrypsin particles in the copolymers containing lactic acid and glycolic acid residues (poly(lactic acid-co-glycolic acid) or PLGA) coated with a cationic hydrophobic surfactant (CTAB) (column 13, example 6). Alavattan et al teaches that the microparticles containing gum arabic and the cationic surfactant (CTAB), not only control the release of the protein from PLGA microparticles, but also stabilize it prior to release over a period of at least about 3 weeks (Table 7) (**claims 1-2, 13, 20, 21** of the instant invention). Alavattan teaches therapeutic bioactive agents include small molecules such as monosaccharides disaccharides and detergents) (column 7, lines 60-66) (**claims 7-8** of the instant invention). Alavattan teaches the microparticles have a particle size range of about 1 to 150 um preferably particle size range of about 5 to 50 um (column 10, lines 6-11) (**claim 17**). Alavattan et al teach the generation of biodegradable and biocompatible microparticles that contain stabilized proteins and also control the kinetics of release of proteins over a period of several weeks under physiological conditions (column 1, lines 11-20). Alavattan et al teach stable protein microparticles encapsulated in hydrophobic poly(lactic-co-glycolic) acid polymers shows almost complete release of protein (about 80% of encapsulated protein is released after 28 days) and can release the protein in a near linear fashion over a period of about one month (column 1, lines 11-20). Alavattan et al suggest a "biologically active protein" in the PLGA

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microparticles includes proteins and polypeptides that are administered to patients as the active drug substance for prevention of or treatment of a disease or condition as well as proteins and polypeptides that are used for diagnostic purposes, such as enzymes used in diagnostic tests or in vitro assays as well as proteins that are administered to a patient to prevent a disease such as a vaccine (column 6, lines 39-46).

However, Alavattan et al do not specifically teach utilizing residues poly(D,L-lactic acid-co-glycolic acid) that comprises the polymer core, in order to produce the polymeric particle. However, prior to the time of the claimed invention, **Newman et al** (J Biomed Mater Res, 60: 480-486, 2002) teach an antigen delivery system by using tetramethylrhodamine dextran loaded poly(D,L-lactic-co-glycolic acid) (PLGA) microspheres at two injection sites (abstract). Newman teaches cellular uptake of tetramethylrhodamine dextran loaded poly(D,L-lactic-co-glycolic acid) (PLGA) microspheres after intraperitoneal immunization, the predominant cell phagocytosing PLGA microspheres in the peritoneal cavity was the macrophage whereas the intradermal immunization resulted in uptake of PLGA microspheres by dendritic cells (abstract) (**claim 5**). Newman et al teach after intraperitoneal immunization, the predominant cell phagocytosing PLGA microspheres in the peritoneal cavity was the macrophage whereas the intradermal immunization resulted in uptake of PLGA microspheres by dendritic cells (abstract).

The combination of prior art cited above in all rejections under 35 U.S.C. 103 satisfies the factual inquiries as set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966). Once this has been accomplished the holdings in KSR can be applied (*KSR International Co. v. Teleflex Inc.* (KSR), 550 U.S. ___, 82 USPQ2d 1385 (2007): "Exemplary rationales that may support a conclusion of obviousness include: (A) Combining prior art elements according to known methods to yield predictable results; (B) Simple substitution of one known element for another to obtain predictable results; (C) Use of known technique to improve

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similar devices (methods, or products) in the same way; (D) Applying a known technique to a known device (method, or product) ready for improvement to yield predictable results; (E) "Obvious to try" – choosing from a finite number of identified, predictable solutions, with a reasonable expectation of success; (F) Known work in one field of endeavor may prompt variations of it for use in either the same field or a different one based on design incentives or other market forces if the variations are predictable to one of ordinary skill in the art; (G) Some teaching, suggestion, or motivation in the prior art that would have led one of ordinary skill to modify the prior art reference or to combine prior art reference teachings to arrive at the claimed invention."

Accordingly, it would have been obvious to the ordinarily skilled artisan to modify the teachings of Alavattan to utilizing poly(D,L-lactic acid-co-glycolic acid) that comprises the polymer core, in order to produce the polymeric particle, such as that taught by Newman, with a reasonable expectation of success. One of ordinary skill in art would have been motivated to make a polymeric particle utilizing poly(D,L-lactic acid-co-glycolic acid) in order to deliver antigens at injection sites since Newman teaches cellular uptake of tetramethylrhodamine dextran loaded poly(D,L-lactic-co-glycolic acid) (PLGA) microspheres after intraperitoneal immunization, the predominant cell phagocytosing PLGA microspheres in the peritoneal cavity was the macrophage whereas the intradermal immunization resulted in uptake of PLGA microspheres by dendritic cells. Although Newman discusses antigen delivery at intraperitoneal and intradermal injection sites by the utilizing poly(D,L-lactic acid-co-glycolic acid) microspheres in the context of APC and dendritic cell uptake, one of skill in the art would readily recognize that an unlimited site of injection sites of said microspheres would also be useful for stable protein microparticles encapsulated in hydrophobic poly(lactic-co-glycolic) acid polymers for almost complete release of protein (about 80% of encapsulated protein is released

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after 28 days) and can release the protein in a near linear fashion over a period of about one month (column 1, lines 11-20), as noted by Alavattan. This is further underscored by the teachings of Alavattan who teach that PLGA microspheres can include therapeutic bioactive agents such as small molecules such as monosaccharides disaccharides and detergents) (column 7, lines 60-66) and as well as proteins that are administered to a patient to prevent a disease such as a vaccine (column 6, lines 39-46).

Thus, the claimed invention, as a whole, is clearly *prima facie* obvious in the absence of evidence to the contrary.

Claims 1, **12** is rejected under 35 U.S.C. 103(a) as being unpatentable over **Alavattan et al** (US 7,060,299) in view of **Newman et al** (J Biomed Mater Res, 60: 480-486, 2002) and further in view of **Singh et al** (PNAS, 97(2): 811-816, 2000).

The teachings of Alavattan/Newman apply here as set forth above.

Alavattan/Newman do not specifically teach the polymetric particle further comprising an adjuvant.

However, at the time of the instant invention **Singh et al** teaches biodegradable microparticles with a cationic surface was developed to improve the delivery of adsorbed DNA into antigen-presenting cells after intramuscular injection (abstract). Singh teaches after i.m. immunization, the microparticles induced significantly enhanced serum antibody responses in comparison to naked DNA, the level of antibodies induced by the microparticles was significantly enhanced by the addition of a vaccine adjuvant, aluminum phosphate (abstract). Singh teaches by the addition of aluminum phosphate to the PLG/CTAB microparticles, resulted in a significantly enhanced response over that achieved with microparticles alone (p 815, 2nd column, 1st paragraph). An important advantage of the microparticle DNA delivery is flexibility,

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allowing additional components, e.g., adjuvant, to be entrapped in the particles carrying DNA, entrapped into separate particles and mixed with DNA particles, adsorbed to the surface of additional particles, or any combination of the above (p 815, 2nd column, 1st paragraph).

The combination of prior art cited above in all rejections under 35 U.S.C. 103 satisfies the factual inquiries as set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966). Once this has been accomplished the holdings in KSR can be applied (*KSR International Co. v. Teleflex Inc.* (KSR), 550 U.S. ___, 82 USPQ2d 1385 (2007): “Exemplary rationales that may support a conclusion of obviousness include: (A) Combining prior art elements according to known methods to yield predictable results; (B) Simple substitution of one known element for another to obtain predictable results; (C) Use of known technique to improve similar devices (methods, or products) in the same way; (D) Applying a known technique to a known device (method, or product) ready for improvement to yield predictable results; (E) “Obvious to try” – choosing from a finite number of identified, predictable solutions, with a reasonable expectation of success; (F) Known work in one field of endeavor may prompt variations of it for use in either the same field or a different one based on design incentives or other market forces if the variations are predictable to one of ordinary skill in the art; (G) Some teaching, suggestion, or motivation in the prior art that would have led one of ordinary skill to modify the prior art reference or to combine prior art reference teachings to arrive at the claimed invention.”

Accordingly, it would have been obvious to the ordinarily skilled artisan to modify the teachings of Alavattan/Mewman to include an adjuvant in the polymeric particle, such as that taught by Singh, with a reasonable expectation of success. One of ordinary skill in art would have been motivated to include an adjuvant in the polymeric particle of Alavattan/Mewman because Singh teaches by the addition of aluminum phosphate to the PLG/CTAB

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microparticles, resulted in a significantly enhanced response over that achieved with microparticles alone (p 815, 2nd column, 1st paragraph). An important advantage of the microparticle DNA delivery is flexibility, allowing additional components, e.g., adjuvants, to be entrapped in the particles carrying DNA, entrapped into separate particles and mixed with DNA particles, adsorbed to the surface of additional particles, or any combination of the above (p 815, 2nd column, 1st paragraph).

Thus, the claimed invention, as a whole, is clearly *prima facie* obvious in the absence of evidence to the contrary.

Claims 1, **18** is rejected under 35 U.S.C. 103(a) as being unpatentable over Alavattan et al (US 7,060,299); Newman et al (J Biomed Mater Res, 60: 480-486, 2002); Singh et al (PNAS, 97(2): 811-816, 2000) and further in view of **Norris et al** (J Appl Poly Sci, 63: 1481-1492, 1997). The teachings of Alavattan/Newman apply here as set forth above.

Alavattan/Newman do not specifically teach the polymeric particle passes through a mucosal barrier at a greater rate than polystyrene particle of a similar size.

However, at the time of the instant invention Norris teaches that the mucin is a barrier to oral absorption of vaccines and vaccine delivery vehicles (VDVs) in vivo (abstract). Norris teaches polystyrene microspheres larger than 0.5 um are limited to diffuse through the mucin layer (abstract). Norris teaches also the surface charge and the hydrophobicity of the polystyrene microspheres play a role on the translocation of the microspheres through the gastrointestinal mucin (title, abstract). Norris teaches ideally, the VDV's must protect the immunogen from GI inactivation, promote transport through biological barriers such as mucin and the interstitial mucosa, augment the immune response, and control the kinetics of vaccine presentation to antigen presenting cell (APCs) thereby promoting an effective immune response

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(p 1481, 2nd column). Norris teaches VDV's must pass through two barriers that are in series: the mucosa and the mucus gel layer. The mucosal tissue acts as a barrier since it restricts the penetration of vaccines, even though it is an incomplete barrier to macromolecules and particulate materials (p 1481, bridge to p 1482).

In view of the facts recited above, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to combine the prior art elements according to known methods to yield predictable results. The prior art teaches all of the limitations of the claimed invention.

The person of ordinary skill in the art could have combined the elements as claimed by known methods to produce the claimed method of delivering an antigen delivery system by using tetramethylrhodamine dextran loaded poly(D,L-lactic-co-glycolic acid) (PLGA) microspheres at two injection sites as taught by Newman and particularly since Newman teaches cellular uptake of tetramethylrhodamine dextran loaded poly(D,L-lactic-co-glycolic acid) (PLGA) microspheres after intraperitoneal immunization, the predominant cell phagocytosing PLGA microspheres in the peritoneal cavity was the macrophage whereas the intradermal immunization resulted in uptake of PLGA microspheres by dendritic cells (abstract). One of skill in the art would have recognized that the results of the combination of a composition comprising the PLGA of Newman in an appropriate size, as taught by the Norris, with a specific a "biologically active protein" in the PLGA microparticles includes proteins and polypeptides to be administered to patients as the active drug substance for prevention of or treatment of a disease or condition as well as proteins and polypeptides that are used for diagnostic purposes, such as enzymes used in diagnostic tests or in vitro assays as well as proteins that are administered to a patient to prevent a disease such as a vaccine, as taught by Alavattan, would have yielded

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nothing more than predictable results to one of ordinary skill in the art at the time the invention was made.

It would also have been obvious to a person of ordinary skill in the art at the time the invention was made to simply substitute one known PGLA size for another to obtain predictable results. One of skill in the art could have readily substituted the polymeric particle size of Alavattan with polystyrene size of Norris in order to promote transport through biological barriers such as mucin and the interstitial mucosa as taught by Norris. Both the level of skill in the art in the field of pharmaceutical science and the microsphere size, surface charge and hydrophobicity, make the size substitution predictable.

Claims 1, **22** is rejected under 35 U.S.C. 103(a) as being unpatentable over Alavattan et al (US 7,060,299); Newman et al (J Biomed Mater Res, 60: 480-486, 2002); Singh et al (PNAS, 97(2): 811-816, 2000); Norris et al (J Appl Poly Sci, 63: 1481-1492, 1997) and further in view of **Baichwal et al** (U.S. Patent No. 5,612,053).

The teachings of Alavattan/Newman/Norris apply here as set forth above.

Alavattan/Newman/Norris do not specifically teach an inhaler.

However at the time of the instant invention Baichwal teaches controlled release powder insufflation formulations containing medicament and a controlled release carrier. Baichwal teaches that the compositions may be prepared by blending fine drug particles (0.1-10 microns) with fine polysaccharide particles (0.1-10 microns) (col. 9, lines 27-31). Baichwal teaches that a wide variety of medicaments can be utilized in the dry powder inhalation/insufflation formulations of the present invention, including anticholinergic agents, corticosteroids, posterior pituitary hormones, cytokines, cytokine inhibitors, polypeptides, peptides, enzymes, genes, gene fragments, hormones (col. 10, lines 1-65). Baichwal teaches that the formulations of his

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invention may be adapted for use with respect to any oral and/or nasal insufflation device for powdered or solid medicaments (col. 11, lines 17-19).

It would have been obvious to a person of ordinary skill in the art at the time of the instant invention to combine the teachings of Alavattan/Newman/Norris and Baichwal, because both inventors teach dry powder pharmaceutical compositions for delivery to the lungs. Inhalation is the delivery of a medicated to the lungs or other body cavity. It would have been obvious to a skilled artisan that oral/nasal inhalation would deliver a medicated PLGA microsphere to the lungs. A skilled artisan would have had a reasonable expectation of success upon combination of the prior art teachings, because both references teach dry powder pharmaceutical compositions wherein the microsphere particles are small (10 microns or less) and are intended for delivery to the lungs.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Magdalene K. Sgagias whose telephone number is (571)272-3305. The examiner can normally be reached on Monday through Friday from 9 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Paras Peter can be reached on 571-272-4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Magdalene K. Sgagias, Ph.D.
Art Unit 1632

/Anne-Marie Falk/
Anne-Marie Falk, Ph.D.
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